(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 October 2003 (09.10.2003)

PCT

(10) International Publication Number
WO 03/082396 A1

(51) International Patent Classification[7]: A61M 25/02, 5/00

(21) International Application Number: PCT/GB03/01377

(22) International Filing Date: 28 March 2003 (28.03.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/368,560 1 April 2002 (01.04.2002) US

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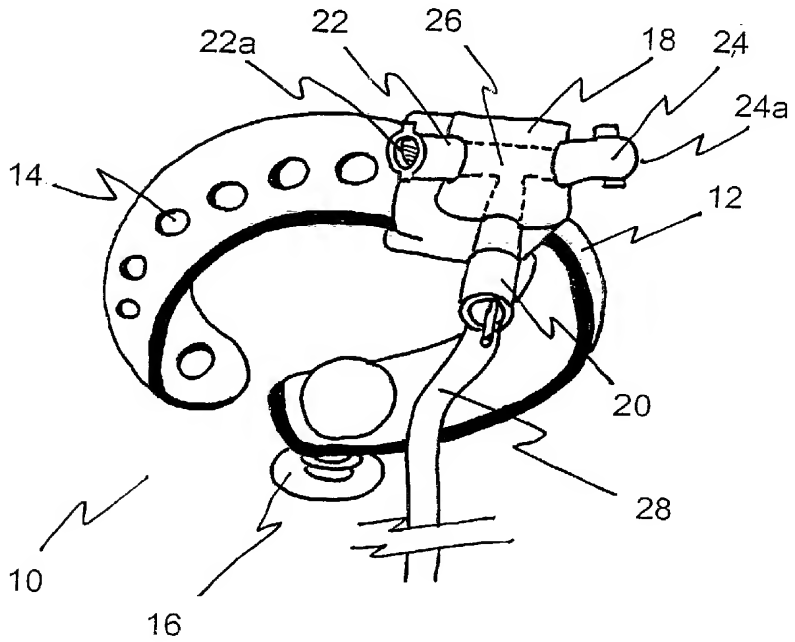
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for all designations*

[Continued on next page]

(54) Title: MULTIPORT INFUSION DEVICE



(57) Abstract: A multiport infusion device used as an intravenous administrator of prescribed fluid is provided. The device includes a band adapted to be secured to a user's body part near an intravenous therapy location. A multiport body is secured to the band and includes a multiport fluid exchange route fluidly communicating between a first port and at least a second port of the body's ports.

WO 03/082396 A1

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations*
— *of inventorship (Rule 4.17(iv)) for US only*

Published:
— *with international search report*
— *with amended claims*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

MULTIPORT INFUSION DEVICE

Field of the Invention

The present invention generally relates to a multiport infusion device and, more particularly, to a device which reduces the risk of extravasation during the administration of intravenous fluids.

Description of the Prior Art

The skin and vein of a patient, whether an infant or an adult, receiving intravenous solutions can be damaged during the initial insertion of an intravenous needle. Similarly, the skin and vein of a patient can be damaged after the procedure by moving the intravenous lines, movement of the patient or by many other known factors. The injury can be caused due to the repeated application and or removal and unintended or inadvertent pulling of the tubes and the like, as well. This, in turn, displaces the needle in relation to the punctured skin site, thus causing damage and injury to the patient. The typical site of such damage includes the hand or arm of the patient, for example.

In known systems, the tube from the reservoir is directly coupled to the extension tube which, in turn, is coupled to the needle of the catheter, itself.

Normally, the intravenous catheter is secured to the patient's skin by an adhesive tape. A further safeguard is the creation of a 'loop' using part of the extended tubing circuit to form a loop and fixed to the skin by an adhesive tape. While the use of a loop can potentially reduce the risk of inadvertent pulls, it will not prevent such pulls and the needle may still be displaced by the movement of the patient or otherwise. Moreover, the use of tapes to secure the tubing can, itself, damage sensitive skin at the point of skin puncture. Indeed, some skin conditions are highly vulnerable to minor trauma brought about by any manipulation.

The prior art is replete with devices for intravenous tubing positioners and holders. However, none of the known devices isolate the extension tube and the reservoir tubing from each other totally. These known devices are also known to cause damage to the skin.

Summary of the Invention

The scope of the invention is defined in the Claims. What follows is a summary, only, of certain inventive features.

In a first aspect of the invention, a multiport infusion device used as an intravenous administrator of prescribed fluid is provided. The device includes a band adapted to be secured to a user's body part near an intravenous therapy location. A multiport body having at least two ports is further provided. The multiport body is secured to the band and includes a multiport fluid exchange route fluidly communicating between a first port and at least a second port.

In embodiments, the band is a flexible band. The first port may accommodate an extension tube extending from a needle and the at least second port may accommodate an intravenous tube in fluid communication with the extension tube. The at least two ports may be three ports or more ports, each one of them may include a sealing cap. The band includes an adjustment mechanism, which may be a plurality of adjustment holes and a fastening device

communicating with the adjustment holes. The band may lie flush with the skin, when in use; whereas the multiport body is raised from the band allowing air circulation between a tube extending from one of the at least two ports and the intravenous therapy location.

In another aspect of the invention, the multiport infusion device includes a flexible band having a first end and a second end and adapted to be secured to a user's body part near an intravenous therapy location. A fastening device is positioned on the flexible band for fastening the flexible band to the user's body part. A main body has a three-way fluid exchange route, each route of the three way fluid exchange route has an opening port. The opening port has a sealing cap adapted to seal the port.

In embodiments of another aspect of the invention, the main body is raised from the flexible band allowing air circulation between a tube extending from one of the ports of the three-way fluid exchange route and the intravenous therapy location. The flexible band includes an adjustment mechanism including the fastening device. A plurality of adjustment holes along the flexible band may be provided for communicating with the fastening device. The flexible band may include means for preventing rotation of the band about the user when placed on the user.

In another aspect of the invention, the multiport infusion device includes a band and means for providing fluid communication routes between an extension tube and at least another tube. Also included is means for preventing rotation of the band.

Brief Description of the Drawings

The foregoing and other objects, aspects and advantages will be better understood from the following detailed description of a preferred embodiment of the invention with reference to the drawings, in which:

Figure 1 shows a perspective view of the present invention; and

Figure 2 shows an illustrative example of the present invention about a user's wrist.

Detailed Description of a Preferred Embodiment of the Invention

The present embodiment is directed to an intravenous device and, more particularly, to an intravenous device which reduces the risk of extravasation during the administration of intravenous fluids. The intravenous device is, in embodiments, a bracelet positioned about the limb or other body part of the user. A peripheral IV is inserted into the device and will act as a 'safe' buffer between the extension and reservoir tubes connected to an angiocath, for example. The intravenous device requires no modification to the currently used reservoir and extension tubes, nor do any known phlebotomy techniques need to be altered.

The device prevents catheter displacements caused by pulls of the tubes secondary to a patient's position change or movements of the IV pole. The use of the intravenous device also directly reduces pressure exerted to the lines and reduces the risk of injuries caused by movements of the limbs or inadvertent displacement of the catheter. Additionally, disengagement and/or exchange of tubing system are greatly simplified. The device also provides additional infusion ports, allowing less manipulation of the tubing and potential dislodgment thereof.

Referring now to Figure 1, the intravenous device is generally depicted by reference numeral 10. The intravenous device 10 includes a band 12, which may be made from a flexible and elastic type material to securely fit over a user's wrist or other portion of any limb or body part. In one embodiment, the band 12 includes adjustment holes 14 communicating with a rivet type device, button or other fastening device 16 placed near or at an end of the band itself. Other fastening or coupling devices may equally be used in order to securely

fit the intravenous device 10 on the user. For example, a tension band or other device may be used.

Still referring to Figure 1, a body 18 having multiple ports 20, 22 and 24 in fluid communication with one another via fluid path 26 is provided on the band 10. In an embodiment, the ports 22 and 24 are positioned substantially at a perpendicular angle to the port 20, and may include caps 22a and 24a, respectively, to seal the ports 22 and 24. The port 20 may also, in embodiments, have a sealing cap. In Figure 1, the caps 22a and 24a are sealing the ports 22 and 24. However, in use, one or both of the caps 22a and 24a can be removed in order to accommodate a tube. The port 20 is preferably used for an extension tube 28 connected to an intravenous needle (not shown). In embodiments more or less than the two additional ports 22 and 24 is also contemplated.

Figure 2 shows the band attached to a user's wrist. This is only one illustrative example and should not be deemed a limiting factor, in any way, of the present invention. As seen in Figure 2, the adjustment mechanism securely fits the band 12 to the user's wrist and prevents rotation thereof. Also, the body 18 is raised from the band allowing air circulation between the tube 28 extending from the port 20 and the intravenous therapy location. This prevents movement of any of the tubes, for example, tube 28 or dislodgment of the needle 28a. In the embodiment shown in Figure 2, the cap 24a is open and the cap 22a remains closed, sealing the port 22. A tube may extend from the port 24 and would thus be in fluid communication with the tube 28 via the fluid communication path 26. The tube connected to the port 24 is used for infusion, as can be a tube connected to port 22. The tubes are isolatable from one another, i.e. can be unplugged individually from their respective ports.

Other aspects and features of the present invention can be obtained from a study of the drawings, the disclosure and the appended claims.

In this description of the invention the intended use of the device is described, for convenience, in relation to the intravenous administration of fluids. It is implicit, of course, that the device may conveniently be used to anchor any flexible connection made between an external device and a point of entry into a human or animal body. For example, the device may be used to anchor naso-gastric tubes, urinary catheters and drain tubes such as chest drains. The term 'intravenous' as used in the description and claims of this application should, therefore, be construed in the broad sense of 'into the body'.

Also for convenience, the description describes the device as being secured 'to a user's body part'. It is clear that the intended use of the device is to prevent damage at the site of entry of the flexible connection into the body. Therefore, in some circumstances, such as where a patient is immobile, it may be equally appropriate to secure the device to a fixed point relative to the patient. Such a fixed point may conveniently be a chair or wheelchair in which a patient is sitting, or a bed in which a patient is lying. References to the term 'user's body part' in the description and claims should therefore be construed in the broad sense of a fixed point relative to the site of entry of a flexible tube into the patient's body.

CLAIMS

1. A multiport infusion device to be used as an intravenous administrator of prescribed fluid, comprising:

a band adapted to be secured to a user's body part near an intravenous therapy location; and

a multiport body secured to the band and including a fluid exchange route communicating between a first port and at least a second port of the body.

2. The multiport infusion device of claim 1, wherein the band is a flexible band capable of being secured about the user's body part.

3. The multiport infusion device of claim 1 or claim 2, wherein one port can accommodate an extension tube extending from a needle and the second port accommodates a tube in fluid communication with the extension tube.

4. The multiport infusion device of claim 1, 2 or 3, wherein there are at least three ports.

5. The multiport infusion device of any preceding claim, wherein one at least of the ports includes a sealing cap.

6. The multiport infusion device of any preceding claim, wherein the band includes an adjustment mechanism.

7. The multiport infusion device of claim 6, wherein the adjustment mechanism includes a plurality of adjustment holes along the band and a fastening device communicating with the adjustment holes.

8. The multiport infusion device of claim 7, wherein the fastening device is a rivet type device or a button placed at or near an end of the band.

9. The multiport infusion device of any preceding claim, wherein the band includes means tending to prevent rotation of the band about the user when placed on the user.

10. The multiport infusion device of any preceding claim, wherein the band is sufficiently flexible as to lie flush with the skin surface of the user when placed on the user.

11. The multiport infusion device of any preceding claim, wherein the multiport body is raised from the band allowing air circulation between a tube extending from one of the ports and the intravenous therapy location.

12. The multiport infusion device of any preceding claim, wherein the ports accommodate respective tubings, the respective tubings being isolatable from one another.

13. The multiport infusion device of any preceding claim, wherein the band is a flexible band.

AMENDED CLAIMS

Received by the International Bureau on 18 August 2003 (18.08.2003) : original claims 1-13 are replaced by amended claims 1-12.

CLAIMS

1. A multiport infusion device to be used as an intravenous administrator of prescribed fluid, comprising:

a band adapted to be secured to a user's body part near an intravenous therapy location; and

a multiport body secured to the band and characterised by the provision of a fluid exchange route communicating between a first port and the or each other port of the body.

2. A multiport infusion device to be used as an intravenous administrator of prescribed fluid, comprising:

a band adapted to be secured to a user's body part near an intravenous therapy location; and

a multiport body secured to the band and characterised by the multiport body being a T-piece form.

3. The multiport infusion device according to either of Claims 1 or 2 wherein the multiport body is in the form of a block.

4. The multiport infusion device of Claim 3, wherein the multiport body is of substantially constant cross-section.

5. The multiport infusion device of any preceding Claim, wherein the band passes through the multiport body.

6. The multiport infusion device of any preceding Claim, wherein the multiport body is raised from the band allowing air circulation between a tube extending from one of the ports and the intravenous therapy location.

7. The multiport infusion device of any preceding Claim wherein the surface of the multiport body that, in use, will be secured, by the band, against the user's skin, is substantially flat.

8. The multiport infusion device of Claim 7 wherein at least one other major external surface of the body is also substantially flat.

9. The multiport infusion device of Claim 7 wherein each other major external surface of the body is also substantially flat.

10. The multiport infusion device of any preceding Claim, wherein one or more of the ports is provided with a sealing cap.

11. The multiport infusion device of Claim 10, wherein the cap or caps is incorporated into the or each port.

12. The multiport infusion device of any preceding Claim, characterised by the absence of any check valve in any one of the fluid flow passages within the body.

Figure 1

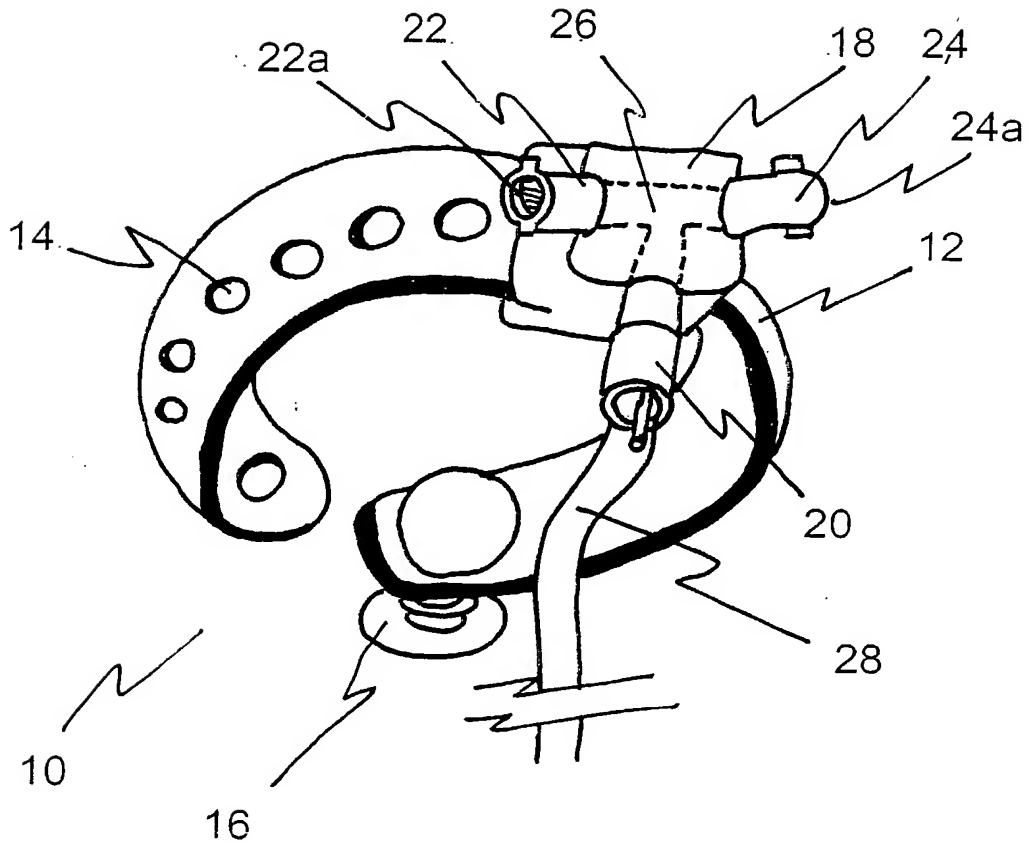
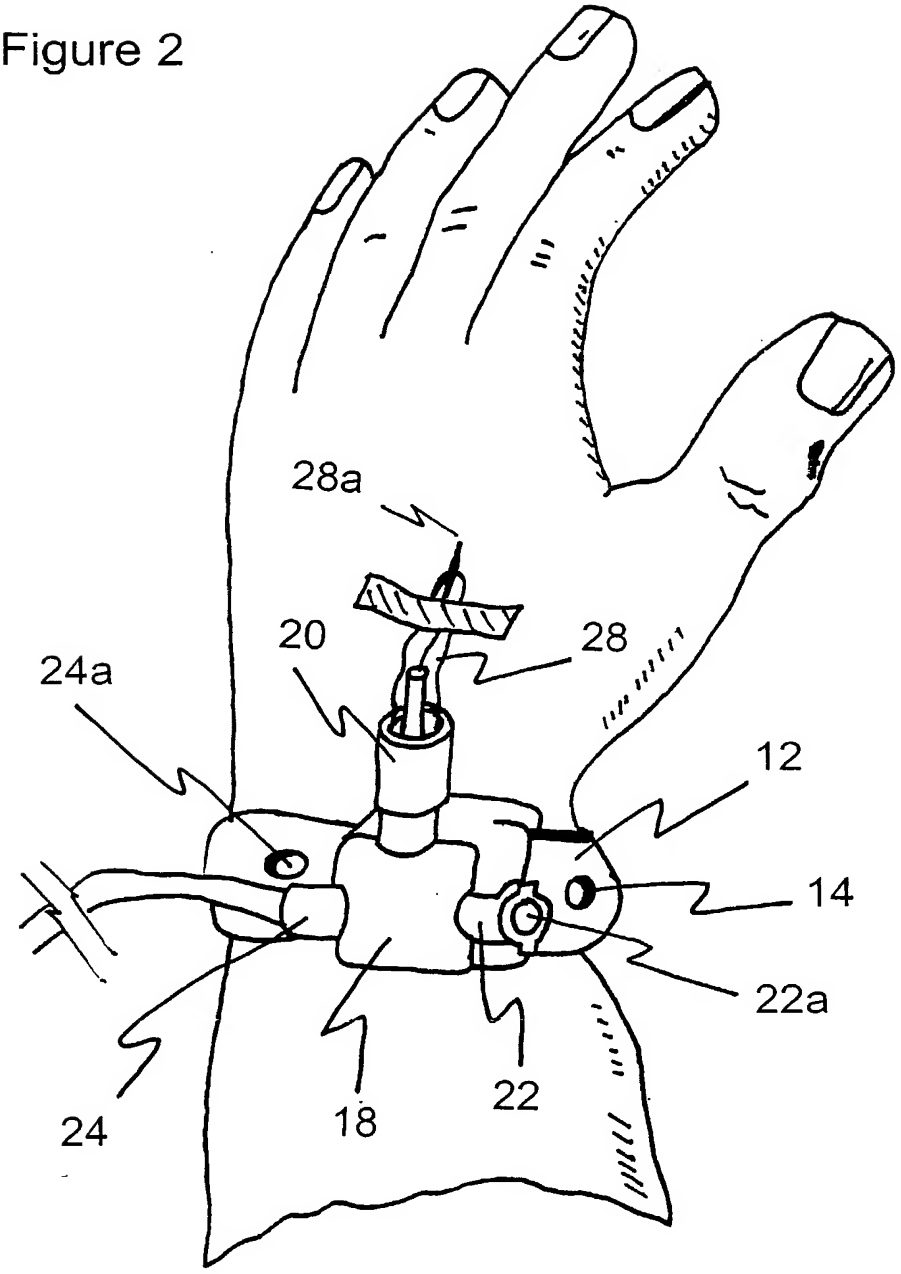


Figure 2



INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/GB 03/01377

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/02 A61M5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 6 086 564 A (MCLAUGHLIN DAVID L) 11 July 2000 (2000-07-11) the whole document ---	1-5,9-13 6-8
Y A	US 4 316 461 A (MARAIS HENRI J ET AL) 23 February 1982 (1982-02-23) the whole document ---	6-8 1-5,9-13
X	US 3 782 382 A (NAFTULIN H ET AL) 1 January 1974 (1974-01-01) column 3, line 1 -column 3, line 54; figures 1,2 ---	1-4,6, 10-13
A	US 2 449 882 A (DANIELS AMY J) 21 September 1948 (1948-09-21) column 1, line 45 -column 2, line 13; figures 1,3 --- -/--	1-11

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 July 2003	14/07/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	PASCAL, A

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 939 832 A (MILLER JOHN J) 24 February 1976 (1976-02-24) column 3, line 51 -column 4, line 24; figure 2 -----	1-11

INTERNATIONAL SEARCH REPORT

Inte nal Application No
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